AMENDMENTS TO THE SPECIFICATION

Please amend the specification as indicated hereafter. It is believed that the following amendments and additions add no new matter to the present application.

In the Specification: [Use ~~strikethrough~~ for deleted matter and underlined for added matter.]

Please replace the title of the invention on page 1, line __ of the Specification section with the following title:

~~ORAL MULTI-FUNCTIONAL PHARMACEUTICAL CAPSULE PREPARATIONS OF PROTON PUMP INHIBITORS~~

PROTON PUMP-INHIBITOR-CONTAINING CAPSULES WHICH COMPRISE SUBUNITS DIFFERENTLY STRUCTURED FOR A DELAYED RELEASE OF THE ACTIVE INGREDIENT

Amendments to the Claims

The following is a marked-up version of the claims with the language that is underlined ("___") being added and the language that contains strikethrough ("—") being deleted:

Listing of Claims

1-48 (CANCELED)

49. (NEWLY ADDED) An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a first population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a first rate;

(ii) a population of a basic substance; and

(iii) a second population of a pharmaceutical active comprising a pharmaceutical active substance releasable at a second rate.

50. (NEWLY ADDED) The composition of claim 49, wherein the first rate of release is faster than the second rate of release.

51. (NEWLY ADDED) The composition of claim 49, wherein the second rate of release is release in at least one of a delayed and sustained manner.

52. (NEWLY ADDED) The composition of claim 49, further comprising a third population of a pharmaceutical active comprising a pharmaceutical active substance being releasable at a third rate.

53. (NEWLY ADDED) The composition of claim 52, wherein the first rate of release is a release in a rapid manner, the second rate of release is release in at least one of a delayed and sustained manner, and the third rate of release is release in at least one of a delayed and sustained manner.

54. (NEWLY ADDED) The composition of claim 49, wherein the oral pharmaceutical composition is a pulsed release capsule.

55. (NEWLY ADDED) The composition of claim 49, wherein at least one of (i), (ii) and (iii) further comprise at least one excipient.

56. (NEWLY ADDED) The composition of claim 55, wherein said at least one excipient is selected from the group consisting of binders, surfactants, fillers, lubricants, disintegrating agents, sustained release agents, and combinations thereof.

57. (NEWLY ADDED) The composition of claim 55, wherein said at least one excipient of (i) to (iii) is present in an amount of about 0.5% to about 95% by weight of said beads, pellets, tablets or granules of said population.

58. (NEWLY ADDED) The composition of claim 55, wherein said at least one excipient of (iii) is a sustained release agent.

59. (NEWLY ADDED) The composition of claim 55, wherein said at least one excipient of (i) serves to release the pharmaceutical active substance of the first population faster than the pharmaceutical active substance of the second population.

60. (NEWLY ADDED) The composition of claim 59, wherein said at least one excipient of (i) is a disintegrating agent.

61. (NEWLY ADDED) The composition of claim 49, wherein the pharmaceutical active of (iii) further comprises an enteric coating.

62. (NEWLY ADDED) The composition of claim 61, wherein a separating layer is provided to separate the pharmaceutical active of (iii) from contact with the enteric coating.

63. (NEWLY ADDED) The composition of claim 49 further comprising (iv) a population of a basic substance, wherein the basic substance is released slower than the basic substance of (ii).

64. (NEWLY ADDED) The composition of claim 63, wherein the basic substance of (iv) further comprises an enteric coating.

65. (NEWLY ADDED) The composition of claim 64, wherein a separating layer is provided to separate the basic substance of (iv) from contact with the enteric coating.

66. (NEWLY ADDED) The composition of claim 49, wherein the pharmaceutical active substance of the first population is the same as the pharmaceutical active substance of the second population.

67. (NEWLY ADDED) The composition of claim 49, wherein at least one of the pharmaceutical active substances of (i) and (iii) comprises an acid labile drug.

68. (NEWLY ADDED) The composition of claim 67, wherein said at least one of the pharmaceutical active substances of (i) and (iii) comprises at least one of a proton pump inhibitor, a prodrug of a proton pump inhibitor, a single enantiomer of a proton pump inhibitor, a single enantiomer of a prodrug of a proton pump inhibitor, and combinations thereof.

69. (NEWLY ADDED) The composition of claim 49, wherein said basic substance is selected from the group consisting of sodium, potassium, calcium, magnesium and aluminum salts of phosphoric acid, carbonic acid, and citric acid; aluminum hydroxide; sodium bicarbonate; aluminum, calcium and magnesium hydroxides; magnesium oxide; trihydroxymethylaminomethane; basic amino acids or their salts; and mixtures thereof.

70. (NEWLY ADDED) The composition of claim 49, wherein (i) provides delivery of the pharmaceutical active to the stomach upon oral administration.

71. (NEWLY ADDED) The composition of claim 49, wherein (iii) provides delivery of the pharmaceutical active between the duodenum and just past the ileocecal junction.

72. (NEWLY ADDED) The composition of claim 49, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach.

73. (NEWLY ADDED) The composition of claim 72, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach.

74. (NEWLY ADDED) The composition of claim 63, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than about 1 hour, wherein the pharmaceutical active of (i) is rapidly or gradually released in the stomach, (iii) provides delivery of the pharmaceutical active between the duodenum and just past the ileocecal junction, and (iv) releases said basic substance just past the ileocecal junction.

75. (NEWLY ADDED) The composition of claim 56, wherein said sustained release agents are selected from the group consisting of pectin, polyvinyl alcohol, polyvinyl acetate, hydroxypropyl cellulose, methylcellulose, ethylcellulose, hydroxypropyl methylcellulose, carragenan, xanthan gum, carbomer and mixtures thereof.

76. (NEWLY ADDED) The composition of claim 56, wherein said disintegrating agents are selected from the group consisting of homopolymer cross-linked N-vinyl-2-pyrrolidone, sodium starch glycolate, cross-linked sodium carboxymethylcellulose and mixtures thereof.

77. (NEWLY ADDED) A method for treating conditions caused by inappropriate gastric acid secretion, said method comprising administering the composition of claim 49 to a subject in need of such treatment.

78. (NEWLY ADDED) The method of claim 77, wherein said inappropriate gastric acid secretion is night time acid secretion and said administration is done at night time.

79. (NEWLY ADDED) An oral pharmaceutical composition comprising multiple populations of at least one of beads, pellets, tablets and granules provided in a capsule, the composition comprising:

(i) a population of a pharmaceutical active;

(ii) a population of a basic substance;

(iii) a population of enteric coated pharmaceutical active; and

(iv) a population of enteric coated basic substance.

80. (NEWLY ADDED) The composition of claim 79, wherein a separating layer is provided to said population of enteric coated pharmaceutical active, said separating layer being provided to separate said pharmaceutical active from contact with said enteric coating.

81. (NEWLY ADDED) The composition of claim 79, wherein a separating layer is provided to said population of enteric coated basic substance, said separating layer being provided to separate said basic substance from contact with said enteric coating.

82. (NEWLY ADDED) The composition of claim 79, wherein at least one excipient is provided to at least one of (i) to (iv).

83. (NEWLY ADDED) The composition of claim 82, wherein said at least one excipient is selected from the group consisting of binders, surfactants, fillers, lubricants, disintegrating agents, sustained release agents, and combinations thereof.

84. (NEWLY ADDED) The composition of claim 82, wherein said at least one excipient is present in an amount of about 0.5% to about 95% by weight of said beads, pellets, tablets or granules of said population.

85. (NEWLY ADDED) The composition of claim 79, wherein at least one over-coating layer is provided to at least one of said population of (i) to (iv).

86. (NEWLY ADDED) The composition of claim 79, wherein said pharmaceutical active comprises an acid labile drug.

87. (NEWLY ADDED) The composition of claim 86, wherein said pharmaceutical active comprises a proton pump inhibitor, a prodrug of a proton pump inhibitor, a single enantiomer of a proton pump inhibitor, a single enantiomer of a prodrug of a proton pump inhibitor, and combinations thereof.

88. (NEWLY ADDED) The composition of claim 79, wherein said basic substance is selected from the group consisting of sodium, potassium, calcium, magnesium and aluminum salts of phosphoric acid, carbonic acid, and citric acid; aluminum hydroxide; sodium bicarbonate; aluminum, calcium and magnesium hydroxides; magnesium oxide; trihydroxymethylaminomethane; basic amino acids or their salts; and mixtures thereof.

89. (NEWLY ADDED) The composition of claim 88, wherein said basic substance is calcium carbonate.

90. (NEWLY ADDED) The composition of claim 79, wherein said population of any one of (i) to (iv) is made by extrusion pheronization or compression into tablets.

91. (NEWLY ADDED) The composition of claim 79, wherein (i) begins delivery of said active in the stomach upon oral administration.

92. (NEWLY ADDED) The composition of claim 79, wherein (i) provides delivery of said active to the stomach, (iii) provides delivery of said active between the duodenum and just past the ileocecal junction and (iv) provides delivery of said active to the ascending, transverse and descending colon.

93. (NEWLY ADDED) The composition of claim 79, wherein (ii) is rapidly released in the stomach and increases the stomach pH to more than about 4 and less than about 7 in less than 1 hour, wherein (i) is rapidly or gradually released in the stomach, (iii) provides rapid or gradual release of active between the duodenum and just past the ileocecal junction and (iv) releases said basic substance just past the ileocecal junction.

94. (NEWLY ADDED) A method for treating conditions caused by inappropriate gastric acid secretion, said method comprising administering the composition of claim 79 to a subject in need or such treatment.

95. (NEWLY ADDED) The method of claim 94, wherein said inappropriate gastric acid secretion is night time acid secretion and said administration is done at night time.

96. (NEWLY ADDED) A method for making the composition of claim 79, said method comprising;

(a) providing a pharmaceutical active or basic substance to a core material to provide a population of (i) and (iii);

(b) providing one or more enteric coating layers to a portion of (a); and

(c) providing (a) and (b) within a capsule.